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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/771,872	02/04/2004	Carina Horn	RDID 03020 US	3760	
67491 DINSMORE &	7590 09/04/200 SHOHL, LLP	EXAMINER			
ONE DAYTON CENTRE			ALEXANDER, LYLE		
SUITE 1300	ONE SOUTH MAIN STREET SUITE 1300		ART UNIT	PAPER NUMBER	
DAYTON, OH	DAYTON, OH 45402			1797	
			MAIL DATE	DELIVERY MODE	
			09/04/2009	PAPER	

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/771,872	HORN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Lyle A. Alexander	1797				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>02 Ju</u>	ne 2009.					
	action is non-final.					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-11 and 14</u> is/are pending in the app	lication.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-11 and 14</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) acce	epted or b)□ objected to by the B	Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1)  Notice of References Cited (PTO-892)	4) ☐ Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:						
Paper No(s)/Mail Date 6) LJ Other:						

10/771,872 Art Unit: 1797

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,378,255. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to redox method using NBD to determine the analyte of interest.

## Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 and 14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horn et al. (USP 7,378,255).

Art Unit: 1797

Horn et al. teach fluorimetric method and reagent for detecting an analyte by a redox reaction using NBD that is substantially identical to the instant claims. Horn et al. qualifies as prior art because the inventive entity is different from the instant application.

The 6/2/09 amendments have added the limitation that an enzyme is required for reducing or oxidizing the analyte. The above cited art all teach enzymatic reactions.

The Office maintains the claims are indistinguishable from the cited prior art.

Claims 1-11 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Albarella et al. (USP 6,872,573), Hoenes(USP 5,334,508) or Ghosh et al.(USP 4,358,595).

Albarella et al., Hoenes and Ghosh et al. all teach fluorescent labels that are indistinguishable from the claimed compound. Albarella et al. teach the addition of cupric compounds and Hoenes oxidoreductase which are reducing agents and cause a redox reaction.

The 6/2/09 amendments have added the limitation that an enzyme is required for reducing or oxidizing the analyte. The above cited art all teach enzymatic reactions.

The Office maintains the claims are indistinguishable from the cited prior art.

## Response to Arguments

Applicant's arguments filed 11/8/07 have been fully considered but they are not persuasive.

Applicant state the Obviousness type double patenting rejections and the 35 USC 102(e) rejections over Horn et al. are not proper. Applicant has stated Horn et al.

and the instant application were commonly owned at the time of the invention which makes Horn et al. unavailable as prior art in a 35 USC 103 rejection based upon 35 USC 103(C). These remarks are not pertinent to the instant Obviousness type double patenting and 35 USC 102(e) rejections because there are no 35 USC 103 rejections over Horn et al. Additionally, 35 USC 103(C) does not overcome Obviousness type double patenting rejections or 35 USC 102(e) rejections.

Page 4

Applicant traverses the Obviousness type double patenting rejections and the 35 USC 102(e) rejections over Horn et al. stating Horne et al. merely lists "NBD derivates" as one possibility and one having ordinary skill in the art would not have chosen the taught "NBD derivative." These remarks are not convincing because Horn et al. clearly teach the claimed "NBD derivative" and has been properly applied.

Applicant remarks directed to Cass and Lakowicz were convincing and these rejections have been vacated.

Applicants' state the instant method claims distinguish over Hoenes by claiming a "fluorimetric determination" rather than a colorimetric determination as taught by Hoenes. However, Hoenes teaches in column 17 lines 15-30 "Lower sample concentrations can be sensitively determined on the basis of the fluorescence ..." which is indistinguishable from the instant claims. The Office maintains the 35 USC 102(b) rejections over Hoenes are proper.

Applicants' state Albarella teaches "NDB-amine" molecules, but fails to teach the generic MNBDH molecule containing an N-oxide. The Office does not understand these

Art Unit: 1797

remarks and maintains that because Albarella teaches "NDB-amine" molecules, it has been properly applied to the pending claims.

Applicants' state Ghosh fails to teach the claimed compound. The Office does not agree and notes Ghosh teaches in claim 1 a composition that is indistinguishable from the instant claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10/771,872 Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/ Primary Examiner, Art Unit 1797 Lyle A Alexander Primary Examiner Art Unit 1797